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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/377,675	08/19/1999	BRADLEY B. OLWIN	2848-32	8188
22442	7590	11/17/2003	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/377,675	OLWIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Olga N. Chernyshev	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,8,10-18,38-41 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,8,10-18 and 43-46 is/are rejected.
- 7) ☒ Claim(s) 47-49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 4, 7 and 9 have been cancelled, claims 1, 2, 3, 6, 7, 10-18 and 38 have been amended and claims 43-49 have been added as requested in the amendment of Paper filed on October 14, 2003. Claims 1-3, 6, 8, 10-18, 38-41 and 43-49 are pending in the instant application.

Claims 38-41 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-3, 6, 8, 10-18 and 43-49 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 6, 8, 10-18 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric FGF-2 protein comprising a biologically active FGF-2 protein having a first amino acid sequence that is at least 70%

identical to an amino acid sequence of FGF-2 represented by SEQ ID NO: 5 or SEQ ID NO: 6 and a penetratin peptide, does not reasonably provide enablement for a chimeric FGF-2 protein comprising a biologically active FGF-2 protein having a first amino acid sequence that is encoded by a nucleic acid sequence that is at least 70% identical to a nucleic acid sequence encoding a FGF-2 represented by SEQ ID NO: 5 or SEQ ID NO: 6 and a penetratin peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-3, 6, 8, 10-18 and 43-47, as amended, are directed to a chimeric FGF-2 protein comprising a biologically active FGF-2 protein having a first amino acid sequence that is encoded by a nucleic acid sequence that is at least 70% identical to a nucleic acid sequence encoding a FGF-2 represented by SEQ ID NO: 5 or SEQ ID NO: 6 and a penetratin peptide. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant invention, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

Claims 1, 43 and 44, as written, encompass a chimeric FGF-2 comprising a first protein which is encoded by a nucleic acid sequence that has percent identity to a nucleic acid sequence

encoding an FGF-2 represented by SEQ ID NO: 5 or 6. Note that recitation “encoded by a nucleic acid sequence that is at least [...] identical to a nucleic acid sequence encoding [an amino acid sequence]” renders the percent similarity and, consequently, structural limitations of the claimed amino acid sequence unpredictable. Claim 1, for example, encompasses chimeric proteins, wherein the first amino acid sequence “is encoded by a nucleic acid sequence that is at least about 70% identical to a nucleic acid sequence encoding” an FGF-2, which allows one to change about 60% of the nucleotides in the claimed nucleic acid. Because three nucleotides (a codon) are required to encode a single amino acid and a change of just one of those nucleotides can change the amino acid encoded by that codon, the structural limitation of claim 1 encompasses a nucleic acid encoding an amino acid sequence differing from that single, naturally occurring amino acid sequence described in the instant specification by up to 90% of the amino acid residues in that sequence. One skilled in the art readily recognizes that claim 1, as written, encompasses a chimeric protein comprising a first protein, which has no structural similarity to FGF-2. The instant specification clearly fails to provide any guidance on how to use the claimed chimeric proteins except for chimeric FGF-2 protein comprising a biologically active FGF-2 protein having a first amino acid sequence that is at least 70% identical to an amino acid sequence of FGF-2 represented by SEQ ID NO: 5 or SEQ ID NO: 6 and a penetratin peptide. Because the instant claimed chimeras appear to be novel, a skilled artisan would not be able to find any support in the art on how to use such proteins and, therefore, would have to solely depend on the guidance presented in the instant specification.

Therefore, because the instant disclosure lacks teachings on how to use the full scope of the claimed invention, and further because of the unpredictability of the art as set forth earlier

and absence of the working examples, the instant specification is not found to be enabling for chimeric FGF-2 proteins comprising a biologically active FGF-2 protein having a first amino acid sequence that is encoded by a nucleic acid sequence that is at least 70% identical to a nucleic acid sequence encoding a FGF-2 represented by SEQ ID NO: 5 or SEQ ID NO: 6 and a penetratin peptide. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 12 is vague and indefinite for recitation "amino acid residues 58 through 43 of SEQ ID NO: 9". The claimed sequence is presented not in numerical order, which makes the subject matter ambiguous. Appropriate correction is required.

#### ***Double Patenting***

7. Applicant is advised that should claim 16 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 16 is directed to a chimeric FGF-2 comprising an amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4, and claim 17 is directed to a chimeric FGF-2 encoded by a nucleic acid sequence of SEQ ID NO: 1 or SEQ ID NO: 3. Because according to the instant specification a nucleic acid of SEQ ID NO: 1 encodes an amino acid sequence of SEQ ID NO: 2 and a nucleic acid of SEQ ID NO: 3 encodes an amino acid sequence of SEQ ID NO: 4, the claimed subject matter of claims 16 and 17 is undistinguishable.

### ***Conclusion***

8. Claims 47-49 if written in independent form are allowable, claims 1-3, 6, 8, 10-18 and 43-46 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

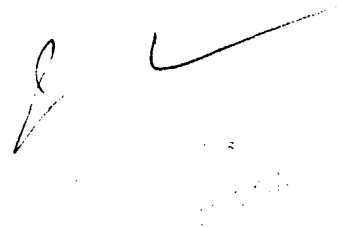
center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.

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